

January 18, 2000 Foundation for the Accreditation of Hematopoietic Cell Therapy

PresidentElizabeth Shpall, M.D.
Denver, Colorado

Vice President
Richard Champlin, M.D.
Houston, Texas

Secretary Adrian Gee, Ph.D. Columbia, South Carolina

*Treasurer*Allen Eaves, M.D., Ph.D.
Vancouver, BC

Board of Directors Nancy Collins, Ph.D. New York, New York

Charles LeMaistre, M.D. San Antonio, Texas

Richard O'Reilly, M.D. New York, New York

Scott Rowley, M.D. Seattle, Washington,

Keith Sullivan, M.D. Seattle, Washington

William Vaughan, M.D. Birmingham, Alabama

Phyllis Warkentin, M.D. Omaha, Nebraska Food and Drug Administration Docket Docket Management Branch HFA-305 Food and Drug Aministration Room-123 Rockville, MD 20857

Re: Docket #97N0497: Request for Proposed Standards for Unrelated Allogeneic Peripheral and Placental Cord Blood Hematopoietic Progenitor-Stem Cell Products Request for Comments

To Docket Management Branch:

The Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT) in collaboration with NETCORD, are respectfully requesting an extension of the deadline for submission to the Docket number listed above until **March 15, 2000**. I spoke to Liana Harvath on January 5, 2000 who thought our request would be acceptable and advised us to formally request the extension by writing this letter to the Docket.

Over the past 18 months, FAHCT and NETCORD have drafted comprehensive standards which cover all aspects of cord blood banking. It has been a huge effort involving cord blood experts from all over the world. These standards are almost finished, but require some additional editing and final review before they can be released. If acceptable, FAHCT will also submit their standards for peripheral blood stem cell collection, processing and transplantaion by March 15, 2000.

We apologize for the delay, and are hopeful that our request for an extension will be granted.

Sincerely,

Blizabeth J. Shpall MD

President, FAHCT

CC FAHCT Board Members
9710-0497 NETCCORD Board Members

EXT 1

JAN 21 A9:14

FAHCT Accreditation Office, Dept. of Pathology/Microbiology, University of Nebraska Medical Center 600 South 42nd Street, Omaha, Nebraska 68198-3135, U.S.A.

Tel: (402) 559-7257 Fax: (402) 559-6018

F	ecex. USA Airbill Tracking 8186 259		tom 0215	Re	Packages up to 150 lbs.
	From This portion can be removed for Recipient's records. Date 7 2 0 0 FedEx Tracking Number	53150	Express Package Service FedEx Priority Overnight Next business morning	PedEx Standard Overnight Next business afternoon	mnitment may be later in some areas. FedEx First Overnight Earliest next business morning delivery to select locations
HERE		2-9000	FedEx 2Day* Second business day	FedEx Express Saver* Third business day	* FedEx Letter Rate not available Minimum charge: One-pound rate
PEEL	Company UNIV OF CO/BONE MARROW TRANSFL	4b	Express Freight Service FedEx 1Day Freight* Next business day	FedEx 2Day Freight	Packages over 150 lbs. Immitment may be later in some areas. FedEx 3Day Freight Third business day.
EZT	Address 4210 E 11TH AVE		Ill for Confirmation:	Second business day	*Declared value limit \$500
RECIPIENT	DENVER State CO ZIP 8022	20	Packaging FedEx Letter*	FedEx Pak*	Other Pkg. Includes FedEx Box, FedEx Tube, and customer pkg.
2	Your Internal Billing Reference	<u> </u>	Special Handling Saturday Delivery Available for English Principle Available for English Princ	ay Delivery a for FedEx Priority HOLD Weekda at FedEx Locati	y HOLD Saturday at FedEx Location Available for FedEx Priority
3	Recipient's HFA - 305 FDA Phone		Available for FedEx Priority Overnight and FedEx 2Day to select ZIP codes Does this shipment contain dangerou One box must be checked.	ht to select ZIP codes Not available with FedEx First Overnight is goods?	Overnight and FedEx 2Day to select locations
	company Docet Managenews Dra	nch [No Yes As per attached Shipper's Declaration Dangerous Goods cannot be shipped in Fede	Yes Shipper's Declaration not required Dry Ice Dry Ice	UN 1845 x kg Cargo Aircraft Only
	Address We cannot deliver to P.D. Power or P.D. 21P codes.	Dept/Floor/Suite/Room	Payment Bill to: Enter	FedEx Acct. No. or Credit Card No. below.	Obtain Recip. Acct No. Cash/Check
:	To HOLD' at Facts location,	•	1 will be billed.		Total Charges
	City State S	<u>60 L</u>		al Weight	Credit Card Auth.
		-		eclare a higher value. See the FedEx Service G authorize delivery without obtaining signature.	uide for details.
		01267993	Ouestions? Call 1'8	eliver this shipment without obtaining a signature to harmless from any resulting claims. 00 • Go • FedEx (800-463-3339)	359
			SRP 1299 • Rev. Date 11/98 • Part #15	4813S • © 1994-38 FedEx-PRINTED IN U.S.A.	